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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/674,750	09/30/2003	Vitaly J. Vodyanoy	035721/267665	4229

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EXAMINER

MONDESI, ROBERT B

ART UNIT PAPER NUMBER

1653

DATE MAILED: 10/19/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.		Applicant(s)	
	10/674,750		VODYANOV ET AL.	
	Examiner		Art Unit	
	Robert B. Mondesi		1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 August 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 20-30 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 20-30 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on August 5, 2005 has been entered.

Status of the claims

Claims 20-30 are presently pending and under examination.

Withdrawal of Objections and Rejections

The objections and rejections not explicitly restated below are withdrawn.

New Objection(s) and Rejection(s)

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 20-30 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claims 20-21 and 30 the applicants cite a method of clearing misfolded proteins from blood comprising contacting a sample with a proteon nucleation center for a limited time and removing the misfolded protein from the sample; however this claim

is indefinite for numerous reasons; the actual term proteon and the phrase "proteon nucleation center" are considered to be indefinite, the mentioned term and phrase are not used in the art, nor are they defined sufficiently in the specification of the present application. On page 2, lines 19-20, of the specification of the present application the applicants have stated that proteons are comprised of misfolded proteins, this can not be considered to be a sufficient definition because the applicants have intentionally or unintentionally insinuated, by using the transitional phrase comprising, that proteons are not necessarily just made up of misfolded proteins but also contain other components, however the applicants have failed to define or explain what other components are included in a proteon. Since the term proteon is not a term of art and appears to be created by the applicants, it is prudent that the applicants provide a concise definition and explanation of the said term. Furthermore it is not clear how the active step of the claim, contacting a sample of blood with a proteon nucleation center, leads to the removing of a misfolded protein from the sample. **Claims 22-29** are dependent claims that do not overcome the deficiencies of the independent claim that they are dependent upon.

Claims 27 and 28 recite the limitation "heating pressure" in line 1. There is insufficient antecedent basis for this limitation in the claim. There is no mention of a heating pressure in independent **claim 21**.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 20 is rejected under 35 U.S.C. 102(b) as being anticipated by Potempa et al., United States Patent No: 5,874,238.

Potempa et al. teach that mutant proteins may be used to remove aggregated immunoglobulin or immune complexes from fluids used for research, in therapeutic procedures, or in diagnostic tests, e.g., solutions containing monoclonal antibodies, antisera, derivatized reagents, intravenous gamma globulin, or isolated blood components. The mutant protein may be bound on a solid support for removing aggregated or complexed immunoglobulins from such fluids. Suitable solid supports are those described above, and the mutant protein is bound to them in the ways described above. Alternatively, the mutant protein may be added directly to such fluids in order to remove the aggregated or complexed immunoglobulins (Column 9 lines, 15-25). It is important to point out that even though Potempa et al. do not specifically point out that a PNC is used in the process of clearing misfolded proteins (aggregated proteins), the reference still applies because the applicants have not sufficiently described a PNC in a manner which a person skill in the art would understand the metes and bounds of the invention. Furthermore it is clear that the method of Potempa et al. would achieve the same end result of the method of the present application. The applicants have not

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defined or clarified how a mutant protein would be different than a PNC; therefore the method of the invention as presently described is anticipated by the disclosure of Potempa et al. Thus Potempa et al. teach all the elements of **claim 20** and this claim is anticipated under 35 USC 102(b).

Claims 21- 22 and 24-27 are rejected under 35 U.S.C. 102(b) as being anticipated by Watanabe et al., 2000.

Watanabe et al. teach that ovalbumin (OVA) was aggregated stepwise by dry heating at 120° C with a gradual increase in its heating times (10min-6h) (DHOVA) (Abstract, lines1-2; Materials and methods: Preparation of samples, lines 6-9).

Watanabe et al. teach that DHOVA samples were solubilized to obtain a concentration of 5% (w/w) and each sample was reheated at 60° C for 3.5 minutes in a water bath and the resultant supernatant was measured followed dilution with 10 mM phosphate buffer according to the method of Lowry et al., 1951 and the coagulated protein ratio (%CPR) was obtained (Materials and methods: Heat aggregation and coagulation of DHOVA, lines 1-12)

Thus Watanabe et al. teach all the elements of **claims 21- 22 and 24-27** and these claims are anticipated under 35 USC 102(b).

Conclusion

No claims are allowed

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert B. Mondesi whose telephone number is 571-272-0956. The examiner can normally be reached on 9am-5pm, Monday-Friday.

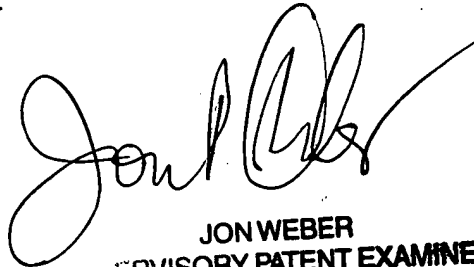
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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Robert B. Mondesi

Robert B. Mondesi
10-16-05


JON WEBER
SUPERVISORY PATENT EXAMINER